[0011] A number of atrial septal defects (ASD) closure devices have been developed and investigated in an attempt to develop a nonsurgical, transvenous method of occlusion of ASD. These include the Sideris Buttoned device, the Angel Wing Das device, the atrial septum defect occlusion system (ASDOS) device, the Amplatz Septal Occluder, the CardioSEAL/StarFlex devices, and the Gore/Helix devices. Unfortunately, each of these devices have distinct disadvantages and limitations ranging from the size of the device delivery sheath, ease of implantation, feasibility, safety and effectiveness. The Sideris buttoned device is made of a polyurethane foam occluder with a Teflon coated wire skeleton, which is positioned within the left atrium, and a polyurethane foam rhomboid shaped counteroccluder with a Teflon coated wire skeleton, which is positioned in the right atrium. The major disadvantage with this device is the lack of a centering mechanism. For this reason, use of the devices at least two times the size of the stretched ASD is required. (Sievert H. Koppeler P. Rux S: Percutaneous closure of 176 interarterial defects in adults with different occlusion devices—6 years of experience [abstract], J. Am. Coll. Cardiol 1999, 33:51 9A.) Consequently, closure of defects may become difficult because the required size may be too large for the atrial septum to accommodate, or the device may impinge critical structures. There are also reports that the retrieval of the Sideris button device after incorrect deployment is difficult. (See, e.g., Rigby, Michael L., The Era of Transcatheter Closure of Atrial Septal Defects, Heart; 81:227-228 (1999)).

[0012] The "Angel Wings" device comprises two square frames made of superelastic Nitinol wire, each square frame having four legs that are interconnected by flexible islets at the comers. The wire frames are covered by polyester fibers. There is a conjoint suture ring of the right and atrial discs, which allow self centering on deployment. The device is delivered through an 11-13 F Mullins sheath. The major disadvantage of using this device is the attendant risk of aortic perforation cause by its sharp eyelet comers. In fact, the Angel Wings device was withdrawn from further clinical trials because of this problem. (Syamaxundar Rao, P., M.D., Summary and Comparison of Atrial Septal Defect Closure Devices, Current Interventional Cardiology Reports 2000, 2:367-376 (2000)). The device is also ill-suited for treating fenestrated defects.

[0013] The atrial septal defect occlusion system (ASDOS) prosthesis (Microvena Corp., White Bear Lake, Minn.) consists of two umbrellas made of Nitinol and a patch of porous polyurethane attached to the left and right atrial devices. The device is introduced transvenously over a long veno-arterial guidewire and through an 11 F venous transeptal sheath. While the device is retrievable in the event of malpositioning before release of the device, it requires a complex procedure to implant, and the components are known to have a high incidences of thrombrosis. It is also reported that frame fractures have been detected in 20% of the patients treated with this device.

[0014] The Amplatzer device is the subject of U.S. Pat. No. 5,944,738 to Amplatzer, et al. This device is a saucer-shaped device formed from a mesh of fine Nitinol wires with a central connecting cylinder having a diameter similar to that of the stretched diameter of the defect. Thrombosis following implantation of the device is induced by three polyester patches. The device is delivered through a 6-10 F Mullins sheath. The primary disadvantage with this device is that it is ill-suited for closing fenestrated defects. Moreover, the device is a thick, bulky profile which dramatically increases the chances that the device will interfere with the heart's operation. Another disadvantage is its known capacity for incomplete endothelialisation with thrombus formation.

[0015] The CardioSEAL® device (NMT Medical is the subject of U.S. Pat. No. 6,206,907 to Marino, et al. This occlusion device is comprised of a center section to which stranded wire elastic shape memory fixation devices are attached. The fixation devices hold the occlusion devices in place once it is inserted into an aperture. Attached to the fixation devices are polyvinyl foam sheets which occlude the aperture. While the CardioSEAL is deemed to be relative easy to use, it is reported that, of all the devices, the CardioSEAL device has the highest incidence of arm fractures, which has raised serious issues concerning its safety. Moreover, the CardioSEAL device, like the Amplatzer device is relatively large, and requiring at least a 10 F or 11 F delivery systems, and an undue amount of hardware within the heart. These characteristics increase the chance that the device will interfere with the heart's operation, lend to residual shunting and/or embolization. The size of the CardioSEAL device also renders it less suitable for small children.

[0016] The STARflex® device (NMT Medical, Inc.) is an updated version of the CardioSEAL device, which includes a self-centering mechanism consisting of four flexible springs which pass between the two fabric disks. While this added feature may reduce the instances of residual shunting, the aforementioned defects and disadvantages of the CardioSEAL are still a concern.

[0017] In view of these drawbacks and related-risks, the method of choice to close a patent foramen ovale is still open heart surgery and ligation of the foramen ovale to close it. Surgery, however, is obviously associated with the usually risks of general anesthesia, open heart procedures, infections, etc. Thus, there is a need for a safe, cost-effective, and easily implantable device and method for preventing the passage of emboli from an arterial blood pool and a venous blood pool which is not subject to the defects and disadvantages of known devices.

## SUMMARY OF THE INVENTION

[0018] The present invention is a directed to an embolic filtering apparatus for treating septal defects, including patent foramen ovales. In one preferred embodiment particularly suited for treating patent foramen ovales, the embolic filtering device comprises an embolic filter, composed of metal, fiber, and/or polymer, for preventing the passage of emboli through the septal defect, and a frame which allows the device to be secured within and or adjacent to the lumen of the septal defect.

[0019] The embolic filter is made by, for example, (1) swaging one end of a piece of tubular mesh at a first end with a first fastener (2) pulling the free end of the mesh over the first fastened end so that it overlaps the first portion; (3) swaging a second, center section of the tubular section to form a 3-dimensional ball-like structure having a first diameter portion with a second fastener; (4) extending the remaining free end of the tubular mesh back over the 3